BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM 37.57.301, 37.57.304, 37.57.305, 37.57.306, 37.57.307, 37.57.308, 37.57.315, 37.57.316, 37.57.320, and 37.57.321, pertaining to newborn screening tests and eye treatment	))))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Interested Persons

1. On December 3, 2007, at 3:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room, 2401 Colonial Drive, Helena, Montana, to consider the proposed amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process (including reasonable accommodations at the hearing site) or who need an alternative accessible format of this notice. If you need an accommodation, contact the department no later than 5:00 p.m. on November 26, 2007. Please contact Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951; telephone (406)444-9503; fax (406)444-9744; e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows. New matter is underlined. Matter to be deleted is interlined.

37.57.301 DEFINITIONS As used in this subchapter, the following definitions apply:

(1) "Health care facility" means a hospital or other facility licensed by or located in the state of Montana for the purpose of providing health care services, and which provides primary health care services for newborns at birth.

~~(1)~~ (2) ~~A~~ "~~n~~Newborn" ~~is~~ means an infant ~~under~~ in the first 28 days of life.

~~(2)~~ (3) ~~"Tests for inborn errors of metabolism"~~ "Newborn screening tests" are ~~include~~ laboratory screening tests for ~~phenylketonuria, galactosemia, congenital hypothyroidism and hemoglobinopathies.~~ the following conditions:

(a) Acylcarnitine Disorders:

(i) Fatty Acid Oxidation Disorders

(A) Carnitice uptake defect

(B) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency

(C) Medium-chain acyl-CoA dehydrogenase deficiency

(D) Trifunctional protein deficiency

(E) Very long-chain acyl-CoA dehydrogenase deficiency

(ii) Organic Acidemia Disorders

(A) 3-OH 3-CH3 glutaric aciduria
(B) 3-methylcrotonyl-CoA carboxylase deficiency
(C) β-ketothiolase deficiency
(D) Glutaric acidemia type I
(E) Isovaleric acidemia
(F) Methylmalonic acidemia (Cbl A,B)
(G) Methylmalonic acidemia (mutase deficiency)
(H) Multiple carboxylase deficiency
(I) Propionic acidemia
(b) Amino Acid Disorders:
(i) Argininosuccinic acidemia
(ii) Citrullinemia
(iii) Homocystinuria (due to CBS deficiency)
(iv) Maple syrup urine disease
(v) Phenylketonuria
(vi) Tyrosinemia type I
(c) Biotinidase deficiency
(d) Classical galactosemia
(e) Congenital adrenal hyperplasia (21 hydrosylase deficiency)
(f) Congenital hypothyroidism
(g) Cystic fibrosis
(h) Hemoglobinopathies, including:
(i) Hb S/B-thalassemia
(ii) Hb SC disease
(iii) Hb SS disease (Sickle cell anemia Hb)

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.304 VERY LOW BIRTH WEIGHT (UNDER 1,500 GRAMS) ~~INFANTS~~ NEWBORNS~~: IN HOSPITAL~~ (1) If a newborn is of very low birth weight, i.e., under 1,500 grams, a ~~sample~~ specimen of its blood must be taken for testing after 24 hours of age and no later than seven days of age, unless medically contraindicated, in which case the ~~sample~~ specimen must be taken as soon as the infant's medical condition permits.

(2) If the ~~infant~~ newborn is not yet feeding when the initial screening ~~sample~~ specimen is collected, a repeat specimen for phenylalanine testing must be taken at least 48 hours following the first ingestion of milk.

(3) In the event that the ~~infant~~ newborn stays in ~~the hospital~~ a health care facility longer than 14 days following birth, a repeat congenital hypothyroid screening must be made either at the time of ~~the hospital~~ discharge~~,~~ if the ~~hospital~~ stay is ~~a month or~~ less than one month, or at one month of age if the ~~hospital~~ stay is one month or longer ~~than one month~~.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.305 ~~INFANTS~~ NEWBORNS OTHER THAN THOSE WITH VERY LOW BIRTH WEIGHT~~: IN HOSPITAL~~ (1) ~~The hospital or institution wherein newborn care was rendered to a newborn weighing 1,500 grams or more must take the required specimen~~ For newborns at birth weights of 1,500 grams or more, the required blood specimen must be taken:

(a) between 24 and 72 hours of age ~~of each newborn~~; or

(b) 48 hours following its first ingestion of milk, but not later than the seventh day of life.

(2) In the event the newborn is discharged from ~~the~~ a health care facility prior to the third day of life, the blood specimen must be taken immediately before discharge and, in addition, if the newborn is discharged before it is 24 hours old:

(a) another specimen must be taken and submitted to the department's laboratory between the fourth and 14th day of the newborn's life; and

(b) the ~~administrative officer or other person in charge of the hospital or institution caring for newborn infants~~ health care facility must:

(i) explain the reasons why it is of utmost importance to return for these tests; and

(ii) ensure that the parent or legal guardian of the newborn signs a statement assuming responsibility to cause a specimen to again be taken between the fourth and 14th day of life of the newborn and to submit it to the department for testing.

(3) If taking a specimen on any of the dates cited in (1) and (2) ~~of this rule~~ is medically contraindicated, the specimen must be taken as soon as possible thereafter as the medical condition of the ~~infant~~ newborn permits.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.306 TRANSFER OF NEWBORN INFANT (1) In the event of transfer of a newborn ~~infant to another hospital or other institution~~ from one health care facility to another, or from a place of birth that is not a health care facility to a health care facility, the specimen required must be taken and submitted by~~:~~ the receiving health care facility unless a sample was taken and submitted by the transferring health care facility or other responsible person.

~~(a) the transferring hospital or other institution if transfer occurs on or after the third day of life; or~~

~~(b) the receiving hospital or other institution if the transfer occurs before the third day of life.~~

(2) ~~A hospital or other institution which receives a newborn who has not been previously tested must take a specimen for testing and submit it to the department's laboratory between the fourth and seventh day of the newborn's life, unless taking a specimen is medically contraindicated, in which case the specimen must be taken as soon as the medical condition of the infant permits.~~ A receiving health care facility must take specimens as necessary for follow-up tests as required by this subchapter.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.307 INFANT BORN OUTSIDE ~~HOSPITAL OR INSTITUTION~~ HEALTH CARE FACILITY (1) When an infant ~~has been~~ is born outside of a ~~hospital or other institution~~ health care facility and ~~has~~ is not subsequently ~~been admitted~~ transferred to ~~such~~ a health care facility for initial newborn care, it is the ~~duty of the~~ responsibility of one of the persons designated in 50-15-221(4)(a), (b), and (c), MCA, in the order of priority indicated therein, to ~~person required in 50-15-201, MCA, to register the birth of that child to~~ cause the blood specimen to be taken and submitted, as required by this subchapter ~~not later than the seventh day of the child's life, unless medically contraindicated, in which case it shall be taken as soon as the medical condition of the infant permits~~.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.308 NEWBORN EYE TREATMENT (1) A physician, nurse-midwife, or any other person who assists at the birth of any ~~infant~~ newborn must, within the time limit stated in (3) below, instill or have instilled into each conjunctival sac of the newborn one of the following:

(a) through (3) remain the same.

AUTH: 50-1-202, MCA
IMP: 50-1-202, MCA

37.57.315 TRANSFUSION: WHEN BLOOD SPECIMEN TAKEN (1) If a newborn needs a transfusion, blood specimens for the tests required by this subchapter must be taken before the transfusion takes place.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.316 ABNORMAL TEST RESULT (1) and (1)(a) remain the same.

(b) the ~~individual~~ person to whom the above report is made must ensure that a second blood specimen is taken within 24 hours of notification and submitted to the department for a second test.

(2) through (3) remain the same.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.320 RESPONSIBILITIES OF REGISTRAR OF BIRTH: ADMINISTRATOR OF ~~HOSPITAL~~ HEALTH CARE FACILITY (1) Each person in charge of any health care facility and each person responsible under ARM 37.57.307 ~~in which a newborn is cared for~~ must:

(a) ~~E~~ensure that a blood specimen is taken from each ~~infant~~ newborn ~~cared for by the facility~~ for which the health care facility or person is responsible, ~~on the schedule noted in the rules in this subchapter~~ in conformity with this subchapter, for the purpose of performing newborn screening tests ~~for inborn errors of metabolism.~~;

(b) ~~B~~be certain, prior to the discharge of the ~~infant~~ newborn, that the specimen to be forwarded to the laboratory is adequate for testing purposes~~.~~;

(c) ~~W~~within 24 hours after the taking of the specimen, cause such specimen to be forwarded to the department's laboratory by first class mail or its equivalent~~.~~; and

(d) ~~R~~record on the ~~infant's~~ newborn's chart or file the date of taking of the test specimen and the results of the tests performed when reported by the department.

~~(2) Each person who is responsible, pursuant to 50-15-201, MCA, for registering the birth of a newborn must ensure that:~~

~~(a) A blood specimen is taken from the infant for which that person is responsible, on the schedule noted in the rules in this subchapter.~~

~~(b) Ensure that the specimen is adequate for testing for inborn errors of metabolism.~~

~~(c) Ensure that the specimen is forwarded to the department's laboratory, by first class mail or its equivalent, within 24 hours after the specimen is taken.~~

~~(d) Record on the newborn's chart, if any, the date the test specimen was taken and the results of the tests performed when reported by the department.~~

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

37.57.321 STATE LABORATORY: RESPONSIBILITY FOR TESTS

(1) Only those ~~laboratory~~ newborn screening tests ~~for inborn errors of metabolism which are~~ performed by the department laboratory or, in the case described in ARM 37.57.316, a laboratory approved by the department, meet the requirements of 50-19-201, 50-19-202, 50-19-203, and 50-19-204, MCA.

AUTH: 50-19-202, MCA
IMP: 50-19-203, MCA

4. These rules expand the current list of screening tests required to be provided to infants born in Montana. Montana currently requires that four screening tests be performed on blood samples taken from newborns to test for a total of six congenital conditions. Senate Bill 162, passed as 2007, Laws of Montana, Chapter 401, by the 2007 Montana legislative session, authorized expansion of the panel of required newborn screening tests through rulemaking. The objective of the Montana legislature in passing Senate Bill 162 was to make sure all infants born in Montana are afforded the best opportunity for diagnosis and treatment of congenital conditions that can result in catastrophic health, financial, and quality of life consequences to newborns and their families, and that the requirements for testing should keep pace with the medical and scientific capacity to diagnose and treat congenital conditions. These amended rules, as proposed, represent the minimum requirements reasonably necessary to give effect to the Legislature's intent, and to provide the greatest opportunity for healthy lives for Montana's children.

ARM 37.57.301 The amendments to this rule include a definition of "health care facility". This term is used, within the rules, as an aggregate identifier of all health

care facilities in Montana that provide primary health care services for newborns at birth, and replaces the terms "hospital" and "institution" as previously used in the rules. The use of this defined term recognizes changes in the health care system, where birthing centers and other nonhospital facilities, now provide primary health care services to significant numbers of newborns.

The definition of the term "tests for inborn errors of metabolism" has been stricken and replaced with a definition of "newborn screening tests". The modification of the defined term recognizes that not all of the tests proposed to be required to be performed on newborns are tests for tests for inborn errors of metabolism.

Most importantly, the amendments to this provision include the addition of 24 screening tests to the panel of tests required to be performed on newborns. Newborns born with these serious congenital conditions may appear to be perfectly healthy at birth and may not display any symptoms of their congenital conditions until serious physical damage or death has occurred. Undiagnosed and untreated, these conditions, variously, may result in organ and nervous system damage, failure to achieve normal physical growth, failure to achieve normal cognitive functioning, chronic ill health, mental retardation, and death. While the expanded panel of screenings is not without financial cost, the financial, emotional, and quality of life costs to afflicted families far outweigh the cost of testing.

The revised list of required newborn screenings brings Montana into line with national standards for newborn screenings. With screening, these congenital conditions can be identified before symptoms develop, and immediate medical intervention with specialized diets, hormone supplements, prophylactic antibiotic treatment, or other measures, can significantly prevent the morbidity and early mortality associated with these conditions.

The department considered adding fewer additional tests to the newborn screening panel, but strongly believes that all of these identified tests are necessary to provide the greatest protection of the health, lives, and futures of Montana's newborns. To exclude any one of these tests would eventually result in delayed diagnosis of that condition for one or more children, likely resulting in pain and suffering, long-term adverse health and developmental consequences, or death where those results may have been avoided. As well, though absolute costs cannot be determined, the financial costs to an afflicted family, the health care system, and society in general for maintenance of a developmentally disabled or mentally retarded individual are very high. The Centers for Disease Control and Prevention estimates that the lifetime cost to society for a person with mental retardation in the United States is $1.1 million (adjusted to 2006 values). The department believes the proposed panel of newborn screening tests provides the minimum testing protocol reasonably necessary to adequately protect the children and families of Montana.

ARM 37.57.307 This rule was amended to clarify what persons are required to ensure newborn screenings for infants born outside of health care facilities. The current rule places responsibility on a "person required in 50-15-201, MCA, to

register the birth of that child" to cause a blood specimen to be taken and submitted for newborn screening testing. Due to modifications in state statutes in prior years, the citation to the MCA in the current rule no longer accurately identifies the state statute related to registration of birth, so the proposed rule updates the citation. Further, the specific designations of individuals responsible to ensure newborn screenings have been amended to no longer include the following persons who may be responsible for registering a birth: the person in charge of the premises where the birth occurred (though a person in charge of a health care facility is still responsible under other provisions of these rules); and the local registrar. The department believes that neither of these classifications of persons who may be required to register a birth will ever be needed, or able, to ensure newborn screenings are performed.

Other minor changes have been made to make the use of defined terms consistent throughout these rules, and to simplify and clarify the requirements.

FINANCIAL IMPACT: The modifications, as proposed, could potentially impact the department financially. Because a significant number of children born in Montana each year are provided health care services through the Medicaid Program, some increased cost for an expanded newborn screening panel could be passed on to the department through higher health care costs. However, because many children afflicted with the long-term health conditions that result from undiagnosed and untreated congenital conditions receive benefits through department programs for health care services and/or developmental disability services, the overall financial impact to the department is expected to be minimal.

5. The department intends the rule changes to be applied effective January 1, 2008.

6. Interested persons may submit comments orally or in writing at the hearing. Written comments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951, no later than 5:00 p.m. on December 6, 2007. Comments may also be faxed to (406)444-9744 or e-mailed to dphhslegal@mt.gov. The department maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. To be included on such a list, please notify this same person or complete a request form at the hearing.

7. An electronic copy of this proposal notice is available through the Secretary of State's web site at http://sos.mt.gov/ARM/Register. The Secretary of State strives to make the electronic copy of this notice conform to the official version of the notice as printed in the Montana Administrative Register, but advises all concerned persons that, in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. The web site may be unavailable at times, due to system maintenance or technical problems.

8. The bill sponsor notice requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by letter dated June 21, 2007, sent postage prepaid via USPS.

9. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct the hearing.

/s/ Denise Pizzini
Rule Reviewer

/s/ Russell E. Cater for
Director, Public Health and Human Services

Certified to the Secretary of State October 29, 2007.